

REMARKS

Claims 1-15, 22-34 are currently pending in the application. Claims 16-21 were previously canceled in the Amendment of October 29, 2003 as being drawn to non-elected inventions. Claims 22-34 are currently canceled. Applicants expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the canceled claims. Claims 3, 4, 7-8 and 12 have been amended. No new matter has been added by way of amendment. Applicants respectfully request reconsideration of the claims in view of the following remarks.

Detailed Action

A. Status of Application

Applicants acknowledge the Information Disclosure Statement filed on October 10, 2003 has been considered. Applicants further acknowledge that the claim of Foreign Priority has been perfected under 35 U.S.C. § 119(a)-(d).

B. Specification

The Examiner has objected to the specification for the "incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication, as claimed on page 1 of the specification".

The application has been amended to remove the "incorporation by reference".

Applicants also submit the specification has now been amended to include the correct date of --2000-- instead of "2001" as can be evidenced by the certified copy of the Canadian Application submitted to the USPTO on November 6, 2003. Applicants have amended the specification to remove this typographical error. Applicants respectfully request that the objection be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claim 8 remains rejected and new claims 22-34 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner states that "Applicants have not described the genus of progeny plants descended from NS2313 (Applicants assume NS3213) that would be required to practice the claimed method of breeding as broadly claimed".

The Examiner states that claim 8 "is directed to a method of using progeny of the exemplified NS3213 Brassica plant in additional breeding steps".

Amended claim 8 defines specific breeding methods that can be utilized in the practice of the present claimed invention. As amended, claim 8 recites breeding steps that do not require the introduction of additional genetics beyond those which are used or produced in claim 7. It is respectfully submitted that the starting materials and methods of breeding are adequately described by the ATCC deposit, the breeding methods described in the specification on pages 7-12 and the Examples and by selection of progeny which have an "R" rating for Blackleg and resistance to at least one AHAS-inhibitor herbicide. The deposit and the disclosure in the present specification are adequate to demonstrate to one skilled in the art that the inventors had possession of the method of amended claim 8.

Claims 22-34 have been canceled. New claims 35-40 are believed to overcome the rejection. New claims 35-40 claim a progeny plant or plant part, seed or cell of variety NS3213 which has an "R" rating for blackleg and resistance to at least one AHAS-inhibitor herbicide. NS3213 is described by representative seed that has been deposited under terms of the Budapest Treaty under ATCC Accession No. PTA-2471. A copy of the ATCC deposit form is enclosed. The parent seed and

distinctive traits of the progeny plant or plant part, seed or cell are clearly defined in the claims. In order to exhibit the traits required by the claim, the progeny plant or plant part, seed or cell must have a sufficient amount of the deposited parent seed genetics to meet the criteria of the claimed traits.

Accordingly, Applicants request that the rejection of claim 8 under 35 U.S.C. §112, first paragraph, be withdrawn.

Enablement

The Examiner has rejected claims 1-15 and new claims 22-34 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims. The rejection is repeated for the reason of record as set forth in the last Office Action mailed 30 July 2003.

The Examiner indicates that the rejection of claim 8 as lacking adequate enablement as outlined in the previous Office Action remains for the reason of record. The Examiner also indicates that the issue is addressed in the above rejection (written description). The Examiner states that Applicant's response "does not address the issue of under what conditions the Deposit of Biological Materials has been made".

Representative seed of varieties NS3213 and 46A76 have been deposited under the Budapest Treaty and given ATCC Accession No. PTA-2471 and PTA-2469 respectively. All restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent. However, Applicant does not waive any infringement of its rights granted under this patent. The specification has been amended to state that the deposit has been made under conditions of the Budapest Treaty.

The Examiner also rejects claims 22-34 for lack of adequate enablement. The Examiner states that the claims are "directed to a myriad of progeny of Brassica plants which Applicant has failed to teach one of skill in the art how to make and use within the meaning of 35 U.S.C. § 112, first paragraph". The Examiner refers to the teachings of *In re Wands* in the previous Office Action.

In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The test of enablement is not whether experimentation is necessary, but rather if experimentation is necessary, whether it is undue. *In re Angstadt*, 198 USPQ 214, 219 (C.C.P.A. 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. In the present case, the experimentation required is routine and has been well described in the specification. The specification also provides working examples of the invention. The skill in the art is high and the claims are commensurate in scope with the disclosure in the specification and the deposit.

Further the sole issue before the *Wands* court was whether the specification enabled the claims in the absence of a deposit. This does not apply to the present case since a deposit of the variety was made and will be available to the public.

The Examiner further states that the applicant provides no guidance on how the exemplified NS3213 Brassica napus plant will recombine with other Brassica plants to produce useable progeny. The art teaches that a canola cultivar needs to

be homogenous, homozygous and reproducible to be useful for the production of a commercial crop on a reliable basis (Patel, US 6,288,307, Col. 7, lines 66-68).

The methods recited in claim 8 are in fact suitable methods for producing such a commercial crop. The methods are described in the present application and are known to those of skill in the art, see pages 7-12 and the examples. Further, it is submitted that an invention need not be of commercial standards in order to be patentable. That is not a criteria required by the laws and rules governing patentable inventions. A *Brassica* variety having the combination of an "R" rating for blackleg and resistance to at least one AHAS-inhibitor herbicide is a valuable contribution to the advancement of agriculture.

Claims 22-34 have been canceled. New claims 35-40 have been added. As discussed above new claims 35-40 claim a progeny plant or plant part, seed or cell of variety NS3213 which has an "R" rating for blackleg and resistance to at least one AHAS-inhibitor herbicide. NS3213 is enabled by representative seed that has been deposited under ATCC Accession No. PTA-2471 and is available to the public. Further the specification describes methods of breeding and selecting progeny plants and plant parts, see pages 7-12 and the Examples in the present application. In order to exhibit the traits required by the claims, the progeny plant or plant part, seed or cell must have appropriate genetic information of the deposited parent seed genetics. These traits and the method of obtaining them in progeny of NS3213 are clearly enabled by the specification and the deposit, see pages 7-12 and the Examples in the present application.

It is respectfully submitted that methods of obtaining homogenous, homozygous and reproducible cultivars are well known in the art. For example backcrossing is described in the '307 patent, Col. 1, line 58 to Col. 2, line 4 and page 10, lines 13-19 of the present application. Backcrossing is frequently used to develop stable cultivars. Other methods are also effective and are well known and described as indicated above, see pages 7-12 and the Examples in the present

application. Such methods are pedigree breeding, self-pollination, haploidy, single seed descent, and modified single seed descent which are described in the present application and are known in the art.

The Examiner further states that the art teaches that the inheritance of blackleg resistance in *Brassica napus* is complex and not completely predictable because different loci that control different types of resistance reside in different genomes (Pang et al 1996, Theor. Appl. Genet. 92:382-387, see especially page 386). As such one of skill in the art would have to determine what other *Brassica* line(s) would recombine in a useful way with the exemplified NS3213 *Brassica napus* line, select useful progeny and then stabilize the segregating population of progeny plants to produce a useful cultivar. It is the Examiner's opinion that given the limited guidance by Applicant for making and using progeny of the exemplified NS3213 *Brassica napus* line, the unpredictability of how two *Brassica* plants will recombine without trial and error experimentation, and the teaching of the art as to what constitutes a useful *Brassica* line, it would have required undue trial and error experimentation by one of skill in the art at the time of the Applicant's invention.

The fact that a trait is complex does not eliminate its effectiveness in a breeding program to achieve desired traits, i.e. a complex trait can be bred and selected for. The present application in conjunction with the deposit, provides sufficient disclosure to produce the products of new claims 35-40, see pages 7-12 and the Examples in the present application.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 1-15 under 35 U.S.C. § 112, first paragraph.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 22-30 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter that Applicant regards as the invention. Specifically, the Examiner has indicated that claims 22-30 are indefinite "because of the sole designation of a plant by its breeding line name or number is arbitrary and creates ambiguity in the claims, in the instant case 'variety NS3213'".

Claims 22-34 have been canceled, therefore the rejection is considered moot. New claims 35-40 contain the ATCC deposit number.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. §§ 102/103

Claims 22, 23, 25, 31 and 33 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Harker *et al.* (Canadian Journal of Plant Science, July 2000, 80(3):647-654) and under 35 U.S.C. § 103(a) as being unpatentable over Harker *et al.* (Canadian Journal of Plant Science, July 2000, 80(3):647-654).

Claims 22-34 have been canceled. New claims 35-40 require a progeny of variety NS3212 having the combination of an "R" rating for blackleg and resistance to at least one AHAS-inhibitor herbicide, representative seed of said variety having been deposited under ATCC Accession No. PTA-2471. Harker *et al.* do not disclose or suggest such progeny.

In light of the above, Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. § 102(b) as anticipated by and, in the alternative, under 35 U.S.C. § 103(a) as obvious over Harker *et al.* (Canadian Journal of Plant Science, July 2000, 80(3):647-654).

Provisional Rejection under Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner has provisionally rejected claims 22-26 and 31-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 14-19 of copending Application No. 09/994,092.

Claims 22-34 have been canceled. New claims 35-40 patentably distinguish over claims 1-5 and 14-19 in U.S. Application No. 09/994,092 by requiring a progeny of variety NS3212 having the combination of an "R" rating for blackleg and resistance to at least one AHAS-inhibitor herbicide, representative seed of said variety having been deposited under ATCC Accession No. PTA-2471.

Applicants respectfully request reconsideration and withdrawal of the current double patenting rejections.

Application No. 09/993,751
Amendment dated 06/15/04
Reply to Office Action of 01/16/04

CONCLUSION

In conclusion, Applicants submit in light of the above amendments and remarks, the current claims are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Respectfully submitted,



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